

REMARKS

This amendment is submitted in response to the outstanding Official Action mailed August 13, 2003. In view of the above claim amendments, the matters discussed during the telephone interview, and the remarks that follow, reconsideration and allowance of this application is respectfully requested.

This amendment follows the November 12, 2003 telephone interview with the Examiner, which is gratefully acknowledged. In the interview, the Examiner was asked where in the cited prior art documents it was disclosed that the claim 1 sapogenins could be formed by deglycosylation of ginsenosides in a single deglycosylation step performed in an aqueous medium using a strong base (alkali metal alcoholate such as hydroxide dissolved in ethanol) under conditions of high temperature and pressure, especially in view of the fact that ether linkages are conventionally cleaved using strong acids. The Examiner responded that it was generally well known that ether linkages can be cleaved using either a strong acid or a strong base.

Applicants respectfully disagree and have canceled the compound and treatment method claims without prejudice (claims 1 - 26 and 35 - 65) to focus prosecution upon their unique method for producing sapogenins. Applicants reserve the right to file Divisional and Continuation Applications directed to the canceled claims.

Claims 27, 31, 33, 34 and 67 - 69 have been amended to more particularly point out and distinctly claim the subject matter that applicants regard as the invention. In particular, claims 27, 33, 34 and 67 - 69 have been rewritten in independent form to incorporate the limitations of canceled claim 1 from which each depends. It is noted for the record that this is a reason unrelated to patentability and merely recites expressly limitations formerly present by implication. These claims have also been amended to clarify that the high temperature and pressure is that which is effective to produce sapogenins from ginsenosides. This is implicitly disclosed in the process description in paragraph 0040 on page 14 of the specification and also implicitly disclosed throughout the examples. No new matter is introduced.

Claim 31 has been amended to state that the alcohol of the alkali metal alcoholate, and not ethanol, has 1-5 carbon atoms. This is clearly a typographical error because ethanol can never have more or less than two carbon atoms. Paragraph 0040 of the description on page 14 at line 18 discloses the alcohol of the alkali metal alcoholate to have 1 - 5 carbon atoms.

For reasons which are submitted below, the claims are believed to be in condition for allowance. Accordingly, reconsideration is respectfully requested.

Turning to the Official Action, the Examiner withdrew newly presented claims 35 - 69 as being directed to independent inventions. Applicants respectfully disagree that claims 66-69 are directed to independent inventions. Claims 35-65 are directed to the use of the inventive sapogenins. Claim 66 depends from claim 27, which is directed to a sapogenin synthesis process. Claims 67 - 69 are directed to sapogenin synthesis process with method limitations narrower than claims the Examiner is willing the examine. The Examiner is respectfully requested to reconsider her position and reinstate and examine claims 66 - 69.

Next, the examiner rejected claims 7, 8, 14, 16 - 23 and 25 under 35 U.S.C. §112, first paragraph for lacking enablement. Without acknowledging the correctness of the Examiner's position, applicants note that these claims have been canceled without prejudice to their presentation in another application, thereby rendering this rejection moot.

Next, the Examiner objected to the amendment to paragraph [0040] presented in the previous amendment as introducing new matter into the disclosure. The examiner stated that the preferable reaction temperature recited was not in the original specification. This objection is respectfully traversed for the reasons set forth hereinafter.

The Examiner did not object to the preferred pressure range, which is gratefully acknowledged. Applicant submits that the preferred temperature range is supported by the original specification much in the same way in Examples 1 and 2 on pages 17 and 18. These Examples disclose that the compounds PAM-120 and PBM-100, which are completely free of glucosyl groups, and PAN-20, which only has one glucosyl group at position 3, are produced by exposing ginseng extract to a temperature of 240°C and 3.5 MPa (shown in Example 1) or 270°C at 4.5 MPa (shown in Example 2). The Examiner did not object to this supporting a preferred pressure range of 3.5 - 8.4 MPa within the broader disclosed range of 2.5 - 8.4 MPa. This likewise supports a preferred temperature range between 240 - 300° C within the broader disclosed range of 150 - 300° C. Applicants submit that no new matter has been added by the amendments reciting a preferred temperature range. Reconsideration by the Examiner and withdrawal of the new matter objection is therefore respectfully requested.

Finally, the Examiner rejected claims 1 - 3, 5, 7 - 10, 12, 14, 16 - 23, 25 and 27 - 34 under 35 U.S.C §103(a) as being unpatentable over Park et al., Yun et al. and Sung Won Kwon et al., essentially for reasons of record. This rejection is respectfully traversed for the reasons set forth hereinafter.

Claims 1 - 3, 5, 7 - 10, 12, 14, 16 - 23 and 25 have been canceled without prejudice to their presentation in another application, so that only claims 27 - 34 remain rejected in view of the cited publications. These claims are directed to processes for the removal of some or all sugar

residues from ginsenoside extracts using a single step in an aqueous medium (following extraction) and a strong base (alkali metal alcoholate such as hydroxide dissolved in ethanol) under conditions of high temperature and pressure. In particular, one or more glucosyl residues are removed from one or more of positions 3, 6 and 24 so that either an H or OH remains at positions 6 and 24 and either an OH or a single glc-O- remains at position 3.

As noted above, in the telephone interview the Examiner acknowledged that none of the prior art publications disclosed the use of caustic under conditions of high temperature and pressure. Specifically, Kwon et al. only obtains ginsenosides by extraction and does not further deglycosylate. Yun et al., deglycosylate ginsenoside extracts using mild acidic hydrolysis, followed by peracetylation, and then direct alkaline treatment.

Park et al. obtains deglycosylate starting materials, either ginsenoside triols with hydroxyl groups at positions 3, 6 and 12 and H at position 24, or diols which differ from the triols only by lack of hydroxyl group or ether at position 6. Park et al. proceed to peracetylate the starting materials with acetic acid and then deacetylate with alkali. A single sugar residue may can be removed from the acetylated diol by the alkali treatment used for deacetylation.

Significantly, none of the cited prior art publications disclose the removal of sugar residues in a single process step following extraction by treatment with caustic under conditions of high temperature and pressure. Instead the cited prior art documents teach against the presently claimed process by either simply performing an extraction step or deglycosylating with a multi-step process.

Regarding the Examiner's position that Applicants' process conditions are otherwise known, Applicants respectfully disagree because glucosyl linkages contain ether bonds that are conventionally cleaved with an acid, as practiced by Yun et al. and Park et al. The Examiner is requested to produce documentary evidence in support of her position as required by MPEP §2144.02.

The documented multi-step processes practiced by Yun et al. and Park et al. instead support the patentability of claims 27 - 34. Omission of an element with retention of its function is an indicia of non-obviousness (see MPEP §2144.04 at page 2100-134). Accordingly, Applicants submit that claims 27 - 34 are not obvious under 35 U.S.C. §103(a) in view of the cited combination of prior art. Reconsideration by the Examiner and withdrawal of this rejection is therefore respectfully requested.

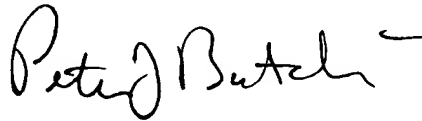
To be complete, Applicants note that process claims 66 - 69 that were withdrawn from consideration patentably define over the prior art of record for the reasons given with respect to claims 27 - 34.

Therefore, in view of the above claim amendments and the foregoing remarks, this application is now in condition for allowance. Reconsideration is respectfully requested. However, the Examiner is requested to telephone the undersigned if there are any remaining issues in this application to be resolved.

Finally, if there are any additional charges in connection with this response, the Examiner is authorized to charge applicant's deposit account number 19-5425 therefor.

Respectfully submitted,

SYNNESTVEDT & LECHNER LLP

A handwritten signature in black ink, appearing to read "Peter J. Butch III", with a horizontal line extending from the end of the signature.

Peter J. Butch III
Reg. No. 32, 203

2600 Aramark Tower
1101 Market Street
Philadelphia, PA 19107-2950
Tele: (215) 923-4466
Fax: (215) 923-2189